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PRODUCE FOR BETTER HEALTH FOUNDATION

March 4, 2004

Division of Dockets Management
HFA–305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir/Ma'am

Comments were submitted electronically on February 25, 2004. This is a courtesy follow-up written submission.

If you have any questions, please do not hesitate to contact me at (302) 235-2329 ext 306.

Thank you.

Sincerely,

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02/25/04

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The Produce for Better Health Foundation (PBH) appreciates the opportunity to provide comments on advanced notice of proposed rulemaking, 21 CFR Part 101, Docket No. 2003N-0496, RIN 0910-AF09, Food Labeling: Health Claims; Dietary Guidance. PBH is the founding partner, along with the National Cancer Institute, for the National 5 A Day for Better Health Program that encourages all Americans to eat 5 to 9 servings of fruits and vegetables each day.

Introduction

PBH supports FDA's efforts and initiatives to increase the truthful and non-misleading information to consumers allowing them to choose foods that contribute to their overall health and vitality. PBH shares the belief that significant public health improvement can be achieved when consumers have scientifically based information available for the food they purchase. PBH also believes that the consumer must be adequately protected from deception and that safeguards assure responsible use of health claims.

FDA Approach to Regulating Qualified Health Claims

FDA is currently seeking comments on three alternative approaches to the regulation of health claims made in the labeling and promotion of dietary supplements and conventional human food. Approach number one is the incorporation of FDA's current interim procedures and evidence-based ranking system described in the July 10, 2003 Consumer Health Information for Better Nutrition Initiative Task Force Final Report into a regulation under notice-and-comment rulemaking.

PBH favors the codification of this approach with changes to the proposed evidence-based ranking system, because it:

- procedurally provides for FDA pre-market review and the opportunity for public participation,
- provides an evidence-based ranking system for evaluating the scientific evidence relevant to the substance/disease relationship addressed in the claim,
- allows for disclaimers that clearly communicate the level of scientific evidence,
- shortens the time required for a health claim petition to be reviewed, and
- provides flexibility for claims to be withdrawn or changed in a timely manner in response to new scientific findings because the claim remains in the form of an enforcement discretion letter instead of a regulation that requires mandatory rulemaking to change.

Although PBH favors an expedient review process, PBH does not support the option of issuing interim final rules as a means of expediting health claims processing as an interim ruling adds complexity to the process and increases the likelihood of consumer confusion.

With regards to the evidence-based ranking system, ranking claims one category beyond significant scientific agreement (SSA) allows for a broader inclusion of claims (B) but beyond that, additional categories (C,D) are viewed by PBH as having a negative effect on consumer confidence. In addition, it seems unlikely that C and D level claims would be useful to the industry. PBH suggests simplification of the ranking system to SSA and a second level maintaining the qualifying language for that level "although there is scientific evidence supporting the claim, the evidence is not conclusive."

Manufacturers Incentives

Clear, succinct qualifying language is important to both the consumer who needs to understand the strength of the supporting science and to the petitioners as it gives them incentives to sponsor research and seek approvals which help them differentiate their products in the marketplace. Other incentives to consider for manufacturers to develop data needed for SSA include tax breaks for research expenses, assistance with identification of research gaps, and federal supplementary research funding programs.

Scientific Review

With regards to the scientific review process, PBH supports broad base input and suggests a revised system that allows the inclusion of industry, academic, consumer group and government agency representation. The consumer will be better served through broad based input.

Consumer Research and Testing

PBH also supports FDA's consumer research efforts and believes that further research is needed to definitively evaluate the ability of alternate approaches to communicate health claims in a way that resonate with the consumer. PBH supports consumer testing of health claims and recommends that simplicity be a guiding principle not only in the construct of new claims but in the review of existing claims. Health claims are of little value if they are too wordy to be included on packaging and in advertisements or too complex to be clearly understood by the consumer. PBH agrees with the use of the terms "FDA approved" or "FDA authorized" and the elimination of the word "may" in claims with SSA as realistic approaches that could be tested with consumers.

Disqualifying Nutrient Levels and Minimum Nutrient Limits

In the light of new information available about the health benefits of monounsaturated fat, fiber, potassium and calcium and the health detriments of trans-fats, PBH supports a re-examination of the disqualifying nutrient levels outlined in 21 CFR 101.14 (a) 4 and

consideration of the need to incorporate this information in a revised definition of "healthy".

PBH identifies with the huge gap between average individual sodium consumption, 4-5 grams per day, and current Institute of Medicine (IOM) recommendations for a Tolerable Upper Intake Level for sodium of 2.3 grams per day. PBH recommends that disqualifying sodium levels reflect realistic targets for step-wise reductions recognizing that the behavioral change needed to reach current recommendations will take time. PBH continues to encourage the consumption of nutrients through whole foods and recommends a conservative approach to fortification.

Dietary Guidance Statements

PBH supports Dietary Guidance Statements giving consumers truthful and not misleading information that guides healthful food selection and consumption. PBH believes however that guidelines be developed for their responsible use. PBH suggests that a product should minimally meet a revised (as recommended above) FDA definition of "healthy" before it can carry a dietary guidance statement

PBH believes that the current definitions of dietary guidance statements and health claims are adequate. PBH applauds the development of and full heartedly supports the fruit and vegetable dietary guidance message, "Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases."

PBH recommends health claims include the substance as the basis of the claim. Claims without the substance inclusion more correctly fall into dietary guidance. PBH agrees the use of food category "substitutions" or "replacements" can be helpful but they need to be carefully crafted.

PBH is willing to provide FDA with additional perspective on this subject and is grateful for the opportunity to comment on this important issue.

Sincerely,

Elizabeth Pivonka

Elizabeth Pivonka, PHD,RD
President, Produce for Better Health Foundation